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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

CONCERNING A FILING UNDER 35 U.S.C. 371

DATE: April 13, 2000

EXPRESS MAIL LABEL NO. EM341130096US

ATTORNEY DOCKET NO. 37418/DBP

APPLICATION NO.

PRIORITY DATE CLAIMED INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE 13.October.1997 13.October.1998 PCT/DE98/03046 TITLE OF INVENTION MR IMAGING METHOD AND MEDICAL DEVICE FOR USE IN METHOD APPLICANT(S) FOR DO/EO/US Andreas Melzer and Martin Busch Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. La This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 2. 🗆 3. X This is an express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). 4. 🗵 A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 5. 🗷 A copy of the International Application as filed (35 U.S.C. 371(c)(2)). a. 🗶 is transmitted herewith (required only if not transmitted by the International Bureau). b.X has been transmitted by the International Bureau. c. \square is not required, as the application was filed in the United States Receiving Office (RO/LUS). 6. 🗷 A translation of the International Application into English (35 U.S.C. 371(c)(2)). 7. \square Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)). a. \square are transmitted herewith (required only if not transmitted by the International Bureau). b. \(\subseteq \) have been transmitted by the International Bureau. c. \square have not been made; however, the time limit for making such amendments has NOT expired. d. \square have not been made and will not be made. 8. \square A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (UNEXECUTED) 10. 🛮 A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items below concern other document(s) or other information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A FIRST preliminary amendment. ☐ A SECOND or SUBSEQUENT preliminary amendment. 14. A substitute specification. 15. \square A change of power of attorney and/or address letter. 16. ☐ Small entity claim with a copy of this transmittal letter attached. 17. X International search report. 18. X International preliminary examination report. 19. X Extra set of drawings 20. KI English Translation of International Application with Annexes to IPER Incorporated. 21. 🗆

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Basic National Fee (37 CFR 1.492(a)(1)-5)):						
Search Report h	as been prepared by the					
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Total Claims	32+7 -20=	19	X \$18	\$ 342.00		
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Note (1): The basic national fee must be paid when filing this application. The 20-month time limit (37 CFR § 1.494) and 30-month time limit (37 CFR § 1.495) are not			nis application. The 20-month mit (37 CFR § 1.495) are not	Amount to be refunde		
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 a. X A check in the amount of \$ 1,572.00 to cover the above fees is enclosed. b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. 						
c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>03-1728</u> . A duplicate copy of this sheet is enclosed.						
NOTE (2): Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.						
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington D.C. 20231-9998 on June 2, 2000.

Sergio F. Chaern

Applicant : Andreas Melzer, et al.

Application No.: 09/529,483 Filed: April 13, 2000

Title : MR IMAGING METHOD AND MEDICAL DEVICE

FOR USE IN METHOD

Grp./Div. : To Be Determined Examiner : To Be Determined Docket No. : 37418/DBP/M521

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS
AND REQUEST FOR REFUND

P.O. Box 7068 Pasadena, CA 91109-7068 June 2, 2000

ry fraid

Commissioner of Patents & Trademarks Washington, D.C. 20231

Commissioner:

Applicant hereby submits a Small Entity Declaration verifying small entity status for the above-identified application. The application was filed on April 13, 2000 with the large entity filing fee of \$1,572.00. The excess over a small entity filing fee is \$786.00. Applicant requests a refund of the excess filing fee under 37 CFR § 1.28(a).

Please refund by check with this firm as payee, and indicate our docket number on the check. A copy of this request is enclosed.

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

D. Bruce Prout

Reg. No. 20,958 626/795-9900

DBP/sfc

Enclosure: Small Entity Declaration

Copy of this request

Docket No. : 37418/DBP/M521

CHRISTIE, PARKER & HALE, LLP

Post Office Box 7068

Applicant or Patentee :

: Andreas Meizer, et al.

Pasadena, CA 91109-7068 (626) 795-9900

Application or Patent No.: Filed or Issued :

To Be AssignedHerewith

Entitled

MR IMAGING METHOD AND MEDICAL DEVICE FOR USE IN

METHOD

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR § 1.9(f) and § 1.27(b)) INDEPENDENT INVENTOR

47 47	
T.	are specification filed forewith.
	Application No filed
	Patent No issued
	I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR § 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR § 1.9(d) or a nonprofit organization under 37 CFR § 1.9(e).
	Each person, concern or organization to which I have assigned, granted, conveyed, or licensed, or am
	under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below.
	is listed below.
	is listed below. No such person, concern or organization. Persons, concerns or organizations listed below. (NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR § 1.28(b))

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR § 1.9(f) and § 1.27(b)) INDEPENDENT INVENTOR

Docket No.: 37418/DBP/M521

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Andreas Melzer	Survey Per Re	13 th April 2000
Name of Inventor	Signature	Date
Martin Busch	Martin Busch	5th April 2000
Name of Inventor	Signature	Date

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant : Andreas Melzer, et al.

Application No. : To Be Assigned Filed : April 13, 2000

Title : MR IMAGING METHOD AND

MEDICAL DEVICE FOR USE IN

METHOD

Grp./Div. : To Be Determined Examiner : To Be Determined Docket No. : 37418 /DBP/M521

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Post Office Box 7068 Pasadena, CA 91109-7068 April 13, 2000

Commissioner:

Please amend the above-identified application as follows:

IN THE BACKGROUND OF THE INVENTION

Page 3, line 1, delete "461" and insert therefor -491-.

IN THE CLAIMS:

Claim 7, line 1, delete "at least one of the preceding claims" and insert therefor -Claim 1-.

Claim 8, line 1, delete "at least one of the preceding claims" and insert therefor -Claim 1-.

Claim 14, line 1, delete "at least one of Claims 9 through 13" and insert therefor -Claim 9-.

Claim 16, line 1, delete "at least one of Claims 9 through 13" and insert therefor -Claim 9-.

Claim 18, line 1, delete "at least one of Claims 9 through 17" and insert therefor -Claim 9-.

Claim 19, line 1, delete "at least one of Claims 9 through 18" and insert therefor -Claim 9-.

Claim 22, line 1, delete "at least one of Claims 9 through 18" and insert therefor -Claim 9-.

Claim 24, line 1, delete "at least one of Claims 9 through 23" and insert therefor -Claim 9-.

Claim 25, line 1, delete "at least one of Claims 9 through 24" and insert therefor -Claim 9-.

Claim 26, line 1, delete "at least one of Claims 9 through 25" and insert therefor -Claim 9-.

Claim 27, line 1, delete "at least one of Claims 9 through 26" and insert therefor -Claim 9-.

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Application No. To Be Assigned

Claim 29, line 1, delete "at least one of Claims 9 through 26" and insert therefor -Claim 9-. Claim 31, lines 1 and 2, delete "characterized by a device according to Claim 7".

Please add new Claim 32 as follows:

32. MR imaging system characterized by a device according to Claim 9.

REMARKS

In view of the foregoing amendment, consideration and allowance of this application is respectfully requested.

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By D. Bruce Prout

Reg. No. 20,958 626/795-9900

DBP/sfc

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09/529483 416 Rec'd PCT/PTO 1.3 APR 2000

MR IMAGING METHOD AND MEDICAL DEVICE FOR USE IN METHOD

Description

The invention relates to an MR (magnet resonance) imaging method for representing and determining the position of a medical device inserted in an examination object according to the generic part of Claim 1 and a medical device for use in the method.

Background of the Invention

MR imaging methods have been known for some time. They are based on the resonance alternating effect between a high-frequency electromagnetic alternating field and specific atomic nuclei of an object to be examined, in particular a human or an animal body that is arranged in a strong external magnetic field. The atomic nuclei precess in the magnetic field (B_o) by the so-called Lamor frequency that is proportional to the strength of the magnetic field. When applying an electromagnetic alternating field whose magnetic alternating component (B_1) is vertical to the direction of the strong magnetic field (B_o), the spins of the atomic nuclei flip and associated relaxation times may thus be measured.

In the description of a scientific model the magnetization of the individual spins is described by total magnetization. This total magnetization in its equilibrium condition is parallel to the

external magnetic field and is called equilibrium magnetization. By means of an HF-impulse applied with the Lamor frequency (resonance frequency), the magnetization may be deflected by an angle α with regard to the direction of the magnetic field. The angle α is proportional to the time period of the HF-impulse applied and the strength of the magnetic field (B_1) of the HF-impulse. Subsequent to an excitation by the angle α , the total magnetization precesses around the direction of the magnetic field. The precessing magnetization may be recorded by a coil that is oriented vertically to the direction of the magnetic field in form of a voltage signal. The strength of the voltage signal is proportional to $\sin(\alpha)$, proportional to the density of the spins in the signal emitting volume and inversely proportional to the temperature.

The maximal signal response of a given volume is thus attained after 90° excitation. The recorded signal amplitude decreases exponentially with the relaxation time T_2^* , since the individual spins fall out of phase due to the fluctuating magnetic fields. Simultaneously, the total magnetization increases exponentially again in the direction of the magnetic field towards the equilibrium magnetization with relaxation time T_1 . By means of magnetic gradient fields switched at the correct point in time, it is possible to image differentiated combinations from the spin density and the two relaxation times in a gray scale encoded image with spatial resolution.

It is further known to locally induce an amplification of the excitation of the nuclear spins by means of a resonance circuit. For this, so called "fiducial markers" are known that have compartments filled with special signal-intensive liquids surrounded by a resonance circuit. (Burl et al.: "Tuned Fiducial Markers To Identify Body Locations with Minimal Perturbation of Tissue

Magnetization", in: Journal of Magnetic Resonance in Medicine 1996, p. 461 - 493.) The resonance circuit has the resonance frequency of the MR system.

If such a fiducial marker is brought into the imaging volume of a nuclear magnetic resonance tomograph, the resonance circuit is excited when electromagnetic radiation is applied at resonance frequency. This results in amplification of the magnetic alternating field within the inductance of the resonance circuit. The increased magnetic component of the magnetic field increases the deflection angle α of the protons within the inductance. With a small angle of excitation (α <90°) of the protons by the nuclear spin system, the protons experience an increased excitation angle within the inductance. In the ideal case, protons are excited with a small angle of 1° to 10° in the imaging volume, whereas the protons within the inductance are excited with 90°. Even with identical relaxation times and with an identical spin density, the signal from the compartment surrounding the resonance circuit is clearly more intensive than the signal of the other parts of the image. Since this signal amplification is localized, it may be used to determine positions.

According to the law of reciprocity, it is also true that the MR response signals of the protons within the compartment surrounding the resonance circuit (fiducial markers) are amplified. Due to the inductance, the magnetic field lines originating from the spins within the coil are bundled such that more signal is emitted from the volume within the inductance and applied to a associated receptor coil. This amplification of emitted and then received signals is considered independent of an increased excitation. Both effects result in a changed signal response of the fiducial marker.

Disadvantageously, fiducial markers make use of separate signal emitting volumina, which for visibility in the MR image must be at least a few cubic millimeters in size and must be placed specifically in the examination object or must be integrated into the systems that are placed in the examination object. Often this is not possible.

With the introduction of open magnets and new techniques with closed MR systems, it has become possible to carry out interventional and minimally invasive techniques such as punction, catherization and surgical processes under MR tomographic control. However, ferromagnetic or paramagnetic metals or impurities in other materials result in artefacts in the images.

Problems result from the tools used for interventional and minimally invasive techniques since they usually consist of ferromagnetic or paramagnetic material and/or that they are so small that they are about the size of one pixel (ca. 1 mm) in MR images. In particular, catheters and implants made of metal or plastics are frequently not visible in the MR image and can best be located by means of artefacts. When materials that are not visible in the MR image are used, they can be seen only as "shadows". These disadvantages result in the fact that MR monitoring of interventional and minimally invasive techniques is frequently unsatisfactory and that an x-ray method with all its known disadvantages is used instead for imaging.

From DE 195 10 194 A1 an active-invasive magnet resonance system for the production of selective MR angiograms is known, whereby an invasive apparatus is provided with an HF coil by which the nuclear spin magnetization of the blood flowing in the vessel is changed locally. By means of special MR image impulse sequences, only the blood that has a changed nuclear spin

magnetization is selectively detected and imaged.

US patent 5,445,151 describes a method for flow measurements in flowing fluids, in particular in blood, whereby the invasive apparatus is provided with at least two HF coils, whereby a local change in nuclear spin magnetization produced by one HF coil is sensed at the other HF coil and the delay interval is used for the computation of flow velocity.

The two publications cited above do not refer to the imaging of medical apparatuses introduced into a body. Furthermore, they have the disadvantage that they are active systems whereby the apparatuses introduced are permanently connected via cable connections to extracorporeal components.

Patent publication DE 195 07 617 A1 describes an MR method whereby a surgical instrument, such as a catheter, is introduced into an examination object whereby the catheter is provided with a micro-coil at its point. The position of the micro-coil is determined by specific sequential techniques.

Object of the Invention

The object of the present invention is to provide an MR imaging method for representing and determining the position of a medical device introduced into an examination object and to provide a medical device suitable for use in the method which allows for clear, signal-intensive imaging of the device in the MR image.

Summary of the Invention

To accomplish this object, the invention is characterized by an MR imaging method with the characteristics of Claim 1 and a medical with the characteristics of Claim 10. Advantageous and preferred embodiments of the invention are reported in the dependent claims.

To accomplish this object, the invention is characterized in that the medical device to be introduced into the examination object is provided with an integrated resonance circuit which induces a changed response signal of the examination object in a locally defined area inside and/or outside the device that is imaged by spatial resolution. The resonance frequency of the resonance circuit is essentially equal to the resonance frequency of the applied high-frequency radiation of the MR imaging system. Since that area is immediately adjacent to the device from inside or outside, the position of the device is clearly recognizable in the correspondingly enhanced area in the MR image. Because a changed signal response of the examined object is induced by itself, only those artefacts appear that are produced by the material of the device itself.

Due to the clear imaging of the device in the MR image a precise position determination is possible. Furthermore, based on the changed signal conditions, improved flow measurement is now possible in the case of a fluid flowing through the device or past the device. Use is made of the fact that different excitation is present inside and outside the device.

The object of the present invention is accomplished as it is based on the surprising discovery that suitable resonance circuits can be provided or arranged on the device in question itself. The

invention preferably provides that the inductance and capacitance providing the resonance circuit are formed by the material of the device, thereby resulting in an additional synergistic effect. It is also within the framework of this invention to provide inductance and capacitance as separate components on the device.

According to the invention, the signal response of the spins within the inductance is changed. Two processes contribute to this. On the one hand, the resonance circuit tuned to the resonance frequency is excited by the application of high-frequency radiation and the nuclear spins detected by the field of the resonance circuit experience amplified excitation through local amplification of the alternating magnetic field in or near the inductance. In other words, protons detected by the field lines of the induced magnetic field are deflected at a larger angle than the protons on the outside of this induced magnetic field. An increased flip of the nuclear spins results.

Accordingly, the signal response sensed by a receptor coil and evaluated for imaging can be amplified. It is furthermore possible that only the spins within the inductance experience saturation and that the signal is diminished with regard to the environment. In both cases, a change in signal response is apparent.

On the other hand - independent of amplified excitation - the MR response signals of the protons within the inductance are amplified. The inductance thus bundles the magnetic field lines originating from the spins within the inductance, which results in an amplified signal emission and an application to an associated receptor coil that receives the amplified signals and transmits them for MR imaging. This effect is described in the publication by J. Tanttu: "Floating Surface Coils", in: XIV ICMBE AND VII ICMP, Espoo, Finland 1985.

According to the present invention, both of these effects may be used in the process of changing the signal response. However, the second effect, i.e., an amplification of the MR response signal, may also be used alone.

Accordingly, a first embodiment of the present invention is characterized in that the application of high-frequency radiation excites the resonance circuit, thus resulting in an amplified excitation of the nuclear spins in the locally defined area.

The locally defined area in which an amplified excitation of the nuclear spins take place may, on the one hand, be located in a compartment formed within the device and surrounded by the inductance. Thus, a volume of the examination object arranged in the interior of the inductance or coil is more strongly imaged. For this, provision is made in particular that the device is elongated and that the axis of the inductance coil runs substantially parallel to the longitudinal axis of the device, whereby the inductance is formed in or on the surface of the device.

On the other hand, this area can be located outside the device and adjacent thereto, whereby at least one resonance circuit is arranged on the surface of the device such that with the application of high-frequency radiation the magnetic flow in the adjacent area observed is amplified. Preferably, the coil axis runs substantially parallel to the longitudinal axis of the device. This variant uses the surrounding medium for signal amplification. However, combinations of the two aforementioned variants are also possible.

A second embodiment of the invention provides, that with the application of the high-frequency radiation the resonance circuit becomes detuned or that the capacitance is short circuited such that no enhanced excitation of the nuclear spins takes place in the locally defined area. However, during measurements of the signal response of the locally defined area, the detuning of the resonance circuit or the short circuiting of the capacitance is canceled again, thus causing the resonance circuit to provide an amplification of the radiated MR response signals of the protons. It was in particular found that this variant makes possible the imaging of the area in and around the device with high quality, i.e., that it provides local imaging beyond the pure position determination. In addition to the position of the device, the MR image provides improved information regarding the structure, etc. of the inside and/or the environment of the device.

An amplification of the excitation of the nuclear spins is, for example, suppressed, in that the condenser of the resonance circuit is short circuited during excitation by means of crossed diodes. The amplification of the emitted signals is thus not influenced, since the small induced voltage from the spins within the inductance is below the conducting-state voltage during emission.

General reference is made to the fact that the change of the signal response according to the invention will usually be an amplification of the signal response. However, this depends on numerous factors, in particular on the excitation sequences used. For instance, with quick consecutive sequences it is possible that a saturation of the excitation of the spins within the inductance is present, thus no signal is produced there. There is, however, no saturation present

in the area outside of the inductance, where a smaller excitation of the nuclear spins takes place, thus a signal is produced here. Correspondingly, in this example, a decrease in the signal response occurs in the area detected by the field of the inductance.

A preferred embodiment of the invention provides that the resonance circuit on the device is formed or activated only after insertion of the device into the examination object, particularly by expansion of the device or of parts of the device. For example, in the case of a balloon catheter, the inductance does not unfold until the inflating of the balloon catheter, whereupon the resonance circuit is formed or activated.

Advantageously, inductance and/or capacitance are adjustable for resonant tuning of the resonance circuit. This makes sense if after introduction of the device into the examination object and a possible expansion of the device or parts of the device, the product of inductance and capacitance, and thus the resonance frequency of the resonance circuit, change.

In an advantageous embodiment of the present invention, at least two resonance circuits are formed or arranged on the device, whereby the coils of the respective inductances are differently aligned, in particular arranged vertically relative to each other or arranged behind each other. Coils aligned vertically relative to each other ensure that in every arrangement of the device in the outer magnetic field, one component of the inductance runs vertical to the field direction of the outer magnetic field, such that a changed signal response is guaranteed. In addition, using suitable sequence techniques, coils arranged behind each other are particularly suited to carry out

a flow measurement (i.e., determination of velocity) of a fluid flowing through or past the device.

Provision is made in a further development of the invention that the inductance of the device is optionally also used as a receptor coil for the acquisition of MR response signals, whereby the inductance is connected by means of a cable link with extracorporeal functional components. This enables additionally using the inductance known from the previously developed methods actively for imaging.

The medical device according to the invention is preferably an implant or a device for implantation, a vena cava filter, a vascular prosthesis, a cardiac valve, a part of a cardiac valve, or a part of an artificial organ, or a diagnostic aid such as a catheter, an endoscope, or an instrument for minimally invasive surgery, such as needles, scissors, forceps, etc.

An MR imaging system according to the invention for performance of the imaging process includes a conventional imaging system and a medical device according to Claim 10.

Description of several exemplary embodiments

Several exemplary embodiments of the invention are explained in the following in detail with reference to the drawing. They depict:

- Fig. 1a, b schematically, two exemplary embodiments of a catheter or guide wire designed according to the invention;
- Fig. 2a-2g various electrical diagrams of a resonance circuit according to the invention;

- Fig. 3a, b two exemplary embodiments of a balloon catheter designed according to the invention;
- Fig. 4 a medical instrument with resonance circuits mounted on the sides of the instrument;
- Fig. 5 a perspective depiction of an alternative embodiment of the medical instrument of Fig. 4;
- Fig. 6a, b two exemplary embodiments of a dental implant designed according to the invention;
- Fig. 7a, b two exemplary embodiments of a joint implant designed according to the invention;
- Fig. 8a, b two exemplary embodiments of a vena cava filter designed according to the invention; and
- Fig. 9a, b two exemplary embodiments of a cardiac valve designed according to the invention.

Fig. 1a and 1b depict a guide wire or catheter 11, on the point of which a resonance circuit consisting of an inductance 2a, 2b and a condenser 3a, 3b is in each case formed. In Fig. 7a [sic], the inductance is formed by a spiral-shaped conductor 2a (solenoid coil) such that the induced magnetic field is aligned substantially vertically relative to the catheter 11 in the surrounding tissue and causes amplified excitation of the nuclear spin there. In Fig. 7b [sic], the inductance is formed by a helix-shaped coil 2b such that the induced magnetic field runs substantially parallel to the longitudinal axis of the catheter 11 and caused amplified excitation of the nuclear spin in

the inside of the catheter 11. The condenser 3a, 3b is in each case implemented by parallel, annular conductor elements. Alternatively, the condenser may also be implemented by a separate structural element which is integrated into the catheter 11.

The inductance 2a, 2b and the capacitance 2a [sic], 3b are preferably formed on a foil, for instance, by means of a photolithographic process. The foil is applied to a flexible hose (not depicted separately). After sealing of the hose and the foil, the hose is applied to the guide wire or catheter 11 such that the arrangement depicted results.

In other embodiments (not depicted) a plurality of resonance circuits according to Fig. 7a [sic], 7b [sic] are arranged along the guide wire or the catheter 11.

Fig. 2a discloses the electrical diagram of the resonance circuit 4 provided in the catheter 11, consisting of inductance 2 and capacitance 3. According to Fig. 2b, an optional additional switch 10 is provided, which can be activated or deactivated electrically or magnetically, for instance, mechanically by means of an activation wire of the catheter 11.

The resonance circuit 4 can be designed in a great variety of embodiments. According to Fig. 2c, it may have several parallel switched inductances 2a to 2n and according to Fig. 2d it may have several parallel switched capacitances 3a to 3n. Furthermore, several inductances and/or capacitances may be serially switched. Several resonance circuits may also be provided on one device which may each have a switch and may have serially and/or parallel switched inductances and/or capacitances.

The resonance circuit 4 has a resonance frequency that corresponds to the high-frequency radiation applied to the MR imaging system in which the human body into which the catheter is inserted, is placed.

In the catheter 1 [sic] according to the invention, the resonance circuit 4 is excited by the applied high-frequency pulses of the MR system, since its resonance frequency corresponds to the frequency of the applied HF-pulse. This results in amplification of the magnetic field in the inductance of the resonance circuit or near the inductance which again may result in an amplified excitation of the protons in the corresponding area. In an excitation of the nuclei outside the area detected by the magnetic field of the inductance by an angle that is smaller than 90°, nuclei within the area detected by the magnetic field of the inductance may experience an excitation of 90° and thus respond at a maximum amplitude. The protons or nuclei arranged in the area of the inductance thus experience a stronger excitation than the protons arranged outside the inductance.

The increase in the deflection angle within the inductance or in the area detected by the magnetic field of the inductance may be up to a factor of 45 in comparison with the protons outside the inductance. It is therefore possible to deflect the protons inside the inductance by an angle of 90° (max. signal response), whereas the protons outside the inductance or outside the magnetic field produced by the resonance circuit, experience no more than a small angle excitation of 2° to 10°. This results in the fact that in the case of Fig. 1b the inside area of the catheter 11 and in the case of Fig. 1a the area adjacent the catheter 11 is imaged substantially brighter in an MR image than the rest of the area. Therefore, the location of the catheter 11 in the human body can be

precisely determined.

An estimate of the required capacitances and inductances follows for the further disclosure of details of the invention. In the exemplary embodiment, a plate condenser is used and the coil is assumed to be a helix with a fixed number of turns. The resonance frequency of a nuclear spin system is usually in the range between 2 MHz to 90 MHz. The resonance frequency of the nuclear spin system is equal to the product of the magnetic field strength and the gyromagnetic relationship g. At a medium field strength of 1 tesla a resonance frequency of ca. 42 MHz results. The resonance frequency of the resonance circuit is determined by Thomson's resonance equation. It is inversely proportional to the root of the product of the inductance and the capacitance.

The product of conductance and capacitance thus is equal 1.4 x 10⁻¹⁹ S². Depending on the number of turns and the catheter 11 of Fig. 1b having an assumed diameter of 8 mm and a coil 2b of a length of 40 mm, an inductance of approx. 4 x 10⁻⁶ Vs/A results. The resultant surface of a plate condenser with a relative dielectric constant of 2 and a distance of 0.1 mm between the individual plates is approx. 0.2 mm². Such a small surface of a plate condenser is easily realized in a catheter. With stronger magnetic fields or frequencies, the resultant surface of a plate condenser can be further reduced to 0.014 mm².

Two additional variants of the invention are disclosed in the diagrams of Figs. 2e through 2g. In Fig. 2e the condenser 3' is short circuited during the excitation phase by means of two crossed diodes 112 that are provided as additional elements in the catheter. The diodes 112 have a

conducting-state voltage of approx. 1 Volt, that is, in any case, below the voltage produced by the application of high-frequency radiation which usually is above 1 Volt. The diodes 112 thus are conductive with the application of high-frequency radiation such that the condenser 3' is short circuited in the excitation phase and thus no resonance circuit is formed.

This means, in contrast to the previous exemplary embodiments, that no increased local excitation of the nuclear spins takes place when high-frequency radiation is applied. However, when measuring the signal response of the region sensed by the inductance 2', the short circuit of the capacitance 3' is canceled again. For this purpose, the diodes 112 are formed in such a manner, that the conducting-state voltage is above the voltage produced during the spin signal response.

Thus, the condenser 3' is not short circuited during the emission of MR response signals of the atomic nuclei and a resonance circuit 4' is formed that effects an amplification of the emitted MR response signals of the protons and thus changes the measured signal response.

The diodes 112 may be realized in a large variety of ways in the catheter. In particular, separate components may be used or the diodes may be formed by or in cooperation with the catheter material, for instance, as a structure mounted on the catheter.

With structures that are in principle the same as those disclosed in Fig. 2e, the condenser 3' in Fig. 2f is not short circuited, but rather the resonance circuit 4' is only detuned in the excitation phase by connecting an additional condenser 113, such that an amplified excitation of the nuclear spins takes place to a limited extent only. During the emission of MR response signals, the diodes 112 lock such that the resonance circuit 4' is not detuned now and an amplification of the

emitted MR response signals takes place, which results in a changed signal response that is imaged in the MR image.

In Fig. 2g the resonance circuit 4" [sic] is not detuned by connecting a condenser but by connecting a coil 114.

It is noted that a short circuiting or a detuning of the resonance circuit can be realized in the excitation phase with any resonance circuits formed or arranged on a medical device, in particular on the devices of Fig. 3a through 9b described in the following.

Fig. 3a, 3b depict in each case a balloon catheter 12 with a resonance circuit. In Fig. 3a, a plurality of spiral-shaped inductances 22a, the axes of which run vertical relative to the longitudinal axis 121 of the balloon catheter, are mounted on the outer skin of the balloon catheter. In Fig. 3b, a helix-shaped inductance 22b, the axis of which runs parallel to the longitudinal axis 121 of the balloon catheter, is provided. Capacitance 32a, 32b is realized in each case on the axis 121 of the balloon catheter 12 in the form of parallel conductors. The inductance 22a, 22b is, for example, formed on a foil, as described in reference to Fig. 1a, 1b.

Various designs of the resonance circuit are possible for the tuning of the resonance frequency of the resonance circuit to the frequency of the applied HF pulse.

In one variant, provision is made that the quality of the resonance circuit is kept relatively low in order to realize a resonance circuit with the broadest possible bandwidth and thus to cover the largest possible range of resonance frequencies.

A second variant discloses providing an apparatus with the capability to keep the product of inductance and capacitance constant even after a change of the geometry as was observed in the example referring to the inflation of the balloon catheter 12. This may take place either in that the balloon catheter is given a geometry that changes its properties as little as possible during unfolding of the balloon catheter, i.e., in particular, it has a constant inductance and a constant capacitance. An inflation of the balloon catheter at the application location thus substantially causes no change in the resonance frequency of the resonance circuit.

Constancy of the product of inductance and capacitance may be realized, among other things, by a compensation of the changing inductance by a correspondingly changing capacitance. For instance, provision is made that the condenser surfaces is [sic] arranged movable perpendicular or parallel to each other for compensation of a changing inductance by a correspondingly changing capacitance, such that the capacitance increases or decreases according to the corresponding distance between the condenser surfaces. For instance, in Fig. 3b, longitudinal movability of the two condenser plates 32b at the time of inflation of the balloon catheter can be provided to compensate the change in inductance at the time of inflation.

A third variant provides that an adjustment of the resonance circuit in the magnetic field of the nuclear spin tomograph is induced by a change or adjustment of the inductance and/or the capacitance of the resonance circuit after their placement. For example, a change of the condenser surface is provided by means of the application instrument located in the body. A decrease in the inductance and thus an adjustment of the resonance circuit to the resonance frequency in the nuclear spin tomograph may take place, for instance, by a laser induced mechanical or electrolytic insulation of coil segments. A change in the capacitance may

also take place by a laser induced mechanical or electrolytic insulation of the capacitance.

Fig. 4 depicts an invasive instrument 9, whereby a plurality of resonance circuits, each consisting of an inductance 7 and a condenser 8, are disposed on the lateral surfaces of the instrument 9. The inductance 7 is designed as a spiral-shaped conductor. This results in the fact that the induced magnetic field is aligned perpendicular to the instrument 9 in the surrounding tissue. Thus, amplification of the excitation is undertaken in the external area adjacent the resonance circuit. In the MR image, the interior of the instrument is not enhanced, but rather the surroundings of the instrument, whereby the position of the instrument is, however, equally easy to identify.

Fig. 5 depicts an alternative embodiment of the instrument of Fig. 4 in a perspective view, whereby it is discernible that on each side of the square-shaped instrument, a spiral-shaped coil arrangement 71, 72, 73, 74 is provided, which form a resonance circuit along with a schematically depicted condenser 8. The induced magnetic field runs in each case perpendicular to the longitudinal axis of the instrument 9'. The induced magnetic field causes amplified excitation of the nuclear spin in the external area adjacent the instrument penetrated by the magnetic field lines, such that in the MR image, this surrounding area can be enhanced and thus it is possible to determine the position of the instrument.

In Fig. 6a, 6b, a resonance circuit according to the invention is formed on a dental implant 13, whereby the axes of the inductances 23a, 23b again run perpendicular (Fig. 6a) or parallel (Fig.

6b) to the longitudinal axis of the dental implant. The condenser 33a, 33b is formed by parallel annular conductors. Fig. 9a [sic] depicts the dental implant with a tooth 14 set on it and Fig. 9a [sic] with the contact point 15 still free.

The inductances and capacitances can again be formed on a foil, which is mounted on the dental implant 13 after sealing. Alternatively, the inductance and/or capacitance can be made of wire or cut from a metal sheet. In a preferred variant, the dental implant 13 is formed as a composite material and the inductance and/or capacitance is incorporated into the material of the dental implant. Arranging the inductive or capacitive elements on the surface of the dental implant 13 is thus avoided.

Fig. 7a, 7b each depict a joint implant 16 with an integrated resonance circuit. The structure and arrangement of the inductances 24a, 24b and capacitances 34a, 34b correspond substantially to those of Fig. 9a, 9b. The capacitance 34a, 34b is in each case designed in the form of two plates arranged one above the other (alternatively: next to each other).

In Fig. 8a, 8b, a resonance circuit is formed in each case on a vena cava filter 17. A vena cava filter is used in particular in a vein for protection against venous thrombosis as a type of funnel. The filter is attached to the vessel wall by means of toothed elements 171. The inductance 25a, 25b is again spiral-shaped (Fig. 8a) or helix-shaped (Fig. 8b). The capacitance 35a, 35b is, for example, again formed by parallel, annular capacitive elements.

The inductances 25a, 25b are preferably cut from metal sheet by laser. They are attached in a suitable manner to the toothed elements 171 and also provide stabilization.

It is likewise possible to form the inductances 25a, 25b and possibly also the capacitances 35a, 35b from the material of the vena cava filter 17. The filter and inductances/capacitances are, for instance, cut from a suitable conducting material by known laser or spark erosion or waterjet cutting techniques.

And finally, Fig. 9a, 9b depict a cardiac valve 18 with a ring 181 which is sutured into the cardiac tissue and on which the actual cardiac valve 182 is arranged. To form a resonance circuit which effects an amplified excitation of the nuclear spin, a condenser 36a, 36b is integrated into the ring 181, for instance, in the shape of parallel annular conductors. In Fig. 9a, solenoid coils 26a, which unfold on the circumference of the ring, are provided as inductances. In Fig. 9b, a toroidal coil 26b is integrated into the ring 181 in addition to the condenser 36b as the inductance of the resonance circuit.

It is noted that with regard to the exemplary embodiments in Fig. 1a, 1b through 9a, 9b, a combination of the various coil arrangements may also be provided in each case.

In a variant of the device according to the invention (not depicted), the device is also used in flow measurements, if a fluid flows through or around it such as, for instance, the vena cava filter of Fig.7. The device then preferably has two resonance circuits arranged following each other whereby the first resonance circuit has two crossed diodes in accordance with Fig. 2e such that

the capacitance is short circuited during excitation, whereas the [sic] resonance circuit is formed without diodes. This results in the fact that during application of high-frequency MR excitation impulses to a subsection of the device, which subsection is surrounded by the resonance circuit without diodes, amplified excitation takes place. However, in the other subsection that is surrounded by the resonance circuit with diodes, a changed signal response now exists compared to the surrounding tissue, as was disclosed with reference to Fig. 2e. With the application of suitable sequence techniques, such an arrangement is particularly effective for the determination of flow and thus for the functional control of the device.

In a further development of the invention (not depicted), provision is made that the inductance of the device itself is used as a receptor coil for the acquisition of MR response signals, whereby the inductance is connected via cable connection to extracorporeal function components. It thus becomes possible to use the inductance of the resonance circuit increasingly actively for the imaging. Due to the necessity of a cable connection to extracorporeal function components this will, however, in general only be possible during a surgical procedure.

The invention is not limited in its embodiment to the previously disclosed exemplary embodiments. Rather, a number of variants which make use of the invention even with fundamentally different types of embodiments, is conceivable.

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Claims

- MR imaging method for the imaging and determination of the position of a unfoldable medical device inserted in an examination object, in particular of a vena cava filter or of a balloon catheter, whereby
 - a) the examination object is arranged in an external magnetic field,
 - b) by means of application of high-frequency radiation of a specific resonance frequency, transitions between spin energy levels of the atomic nuclei of the examination object are excited and
 - c) MR signals thus produced are detected as signal responses, evaluated, and imaged in spatial resolution,

characterized

in that, in a locally defined area inside and/or outside the device, a changed signal response of the examination object is produced whereby the device has or forms at least one passive resonance circuit with an inductance and a capacitance whereby their resonance frequency is essentially equal to the resonance frequency of the applied high-frequency radiation, whereby an unfoldable part of the device forms the inductance or is integrated therein, this unfoldable part is unfolded after insertion of the device in the examination object and the area is imaged with the changed signal response in spatial resolution.

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- 2. Method according to Claim 1, **characterized in** that the application of the high-frequency radiation excites the resonance circuit and thus an amplified excitation of the nuclear spins of the examination object results in the locally defined area.
- 3. Method according to Claim 2, **characterized in** that the locally defined area where an amplification of the excitation of the nuclear spins takes place is located in a compartment formed within the device and surrounded by the inductance.
- 4. Method according to Claim 2, **characterized in** that the locally defined area where an amplification of the excitation of the nuclear spins takes place is outside the device and adjacent thereto, whereby at least one resonance circuit is arranged on the surface of the device such that with the application of high-frequency radiation the magnetic flow in the adjacent area observed is amplified.
- 5. Method according to Claim 1, **characterized in** that with the application of the high-frequency radiation the resonance circuit becomes detuned or the capacitance is short circuited to the extent that no amplified excitation of the nuclear spins takes place in the locally defined area, whereas by measuring of the signal response of the locally defined

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area the detuning of the resonance circuit or the short circuiting of the capacitance is canceled, thus resulting in a change in the signal response.

- 6. Method according to at least one of the preceding claims, **characterized in** that the resonance circuit is adjusted to the resonance frequency by unfolding of the device after insertion of the device into the examination object.
- 7. Method according to at least one of the preceding claims, **characterized in** that the inductance and/or the capacitance are adjusted for the resonant tuning of the resonance circuit.
- 8. Method according to at least one of the preceding claims, **characterized in** that at least two resonance circuits formed or arranged on the device are used, whereby the coils of the respective inductances are arranged differently, in particular aligned vertically to each other or behind each other.
- 9. Unfoldable medical device, in particular a vena cava filter (17) or of a balloon catheter (12),

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by at least one passive resonance circuit with an inductance (22a, 22b, 25a, 25b) and a capacitance (32a, 32b, 35a, 35b), whose resonance frequency is essentially equal to the resonance frequency of the applied high-frequency radiation of an MR imaging system, whereby an unfoldable part of the device forms the inductance (22a, 22b, 25a, 25b) or the inductance (22a, 22b, 25a, 25b) is integrated into such a part, such that it unfolds along with the device when this is unfolded.

- 10. Device according to Claim 9, **characterized in** that the inductance (22a, 22b, 25a, 25b) is formed or arranged on the surface of the device.
- Device according to Claim 9 or 10, **characterized in** that the inductance (22a, 22b, 25a, 25b) is formed by a conductor which runs on the surface of the device.
- 12. Device according to Claim 11, **characterized in** that the inductance (22a, 22b) is formed on a foil which is adhered to the surface of the device (12).

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- 13. Device according to Claim 8 or 10, **characterized in** that the inductance (25a, 25b) and/or the capacitance (35a, 35b) are formed from the material of the device (17).
- 14. Device according to at least one of Claims 9 through 13, **characterized in** that the device (12, 17) is elongated in shape and the coil axis of the inductance (22b, 25b runs substantially parallel to the longitudinal axis of the device (12, 17).
- 15. Device according to Claim 14, **characterized in** that the inductance is formed by a conductor arranged on the surface of the device in the shape of a single, double or multiple helix.
- 16. Device according to at least one of Claims 9 through 13, characterized in that the device (12, 17) is elongated in shape and the coil axis of the inductance (22a, 25a) runs substantially perpendicular to the longitudinal axis of the device (12, 17).
- 17. Device according to Claim 16, **characterized in** that the inductance is formed by a spiral-shaped conductor (22a, 25a) formed or arranged on the surface of the device.

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- 18. Device according to at least one of Claims 9 through 17, **characterized in** that the device has a plurality of resonance circuits with a plurality of inductances, which are preferably arranged vertically relative to each other or arranged behind each other.
- 19. Device according to at least one of Claims 9 through 18, **characterized in** that the device has means (113) for detuning at least one resonance circuit with the application of high-frequency radiation.
- 20. Device according to Claim 19, **characterized in** that the means for detuning the at least one resonance circuit are designed such that they switch a condenser (113) parallel to the capacitance (3') of the resonance circuit with the application of high-frequency radiation.
- 21. Device according to Claim 19, **characterized in** that the means for detuning the at least one resonance circuit are designed such that they switch a coil (114) parallel to the inductance (2') of the resonance circuit with the application of high-frequency radiation.

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- 22. Device according to at least one of Claims 9 through 18, **characterized in** that the device is provided with means (112) for the short circuiting of the capacitance (3') when applying the high-frequency radiation.
- 23. Device according to Claim 22, **characterized in** that the means for the short circuiting of the capacitance have two diodes (112) which are switched parallel to the capacitance (3').
- 24. Device according to at least one of Claims 9 through 23, **characterized in** that a switch (10) is provided, by which the at least one resonance circuit can be activated or deactivated.
- 25. Device according to at least one of Claims 9 through 24, **characterized in** that the inductance (2) and/or the capacitance (3) of the resonance circuit are adjustable for the tuning to the resonance frequency of the MR system.
- 26. Device according to at least one of Claims 9 through 25, characterized in that the resonance circuit (4) has a plurality of parallel or serially switched inductances (2a, 2n) and/or capacitances (3a, 3n).

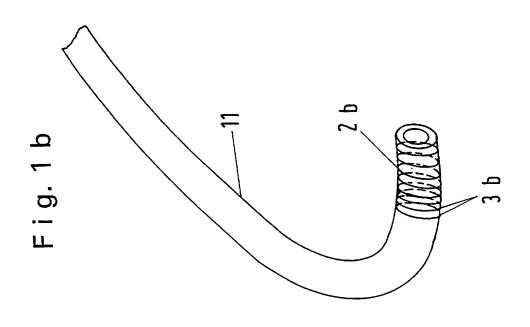
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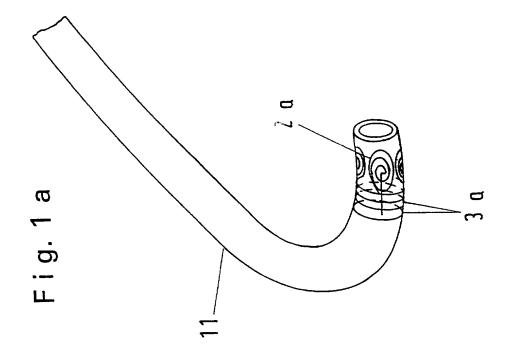
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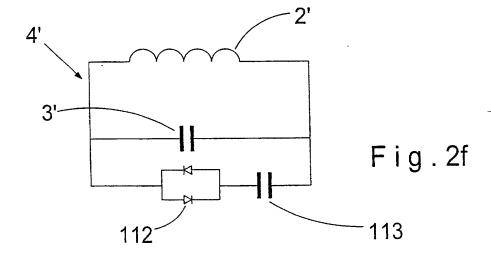
- 27. Device according to at least one of Claims 9 through 26, **characterized in** that the device is a balloon catheter (12), on whose outer skin a spiral-shaped or helix-shaped inductance (22a, 22b) is formed.
- 28. Device according to Claim 27, **characterized in** that the capacitance (32a, 32b) is realized in the form of parallel conductors which run along the axis (121) of the balloon catheter (12).
- 29. Device according to at least one of Claims 9 through 26, **characterized in** that the device is a vena cava filter (17) with elongated, movable toothed elements (171), whereby the inductance (25a, 25b) is attached to the toothed elements.
- 30. Device according to Claim 29, **characterized in** that the inductance (25a, 25b) and/or the capacitance (35a, 35b) are made of the material of the vena cava filter.
- 31. MR imaging system for performance of the method according to Claim 1, characterized by a device according to Claim 7 [?sic].

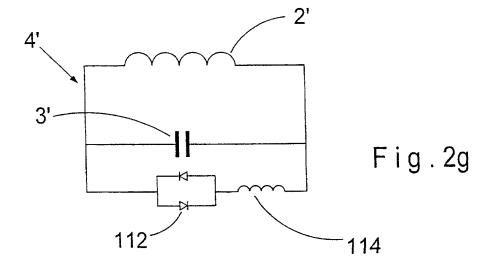




2/10 Fig.2a- 3 10 Fig.2b - 3 2a 2n Fig.2c 3a -Fig.2d 3n

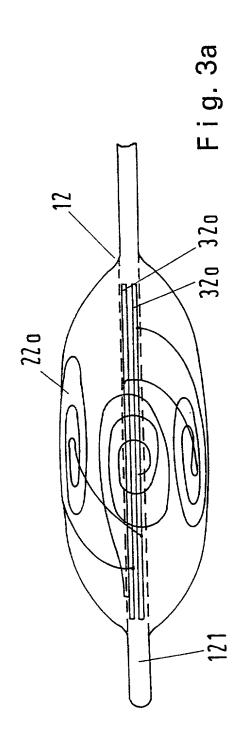
Fig.2e

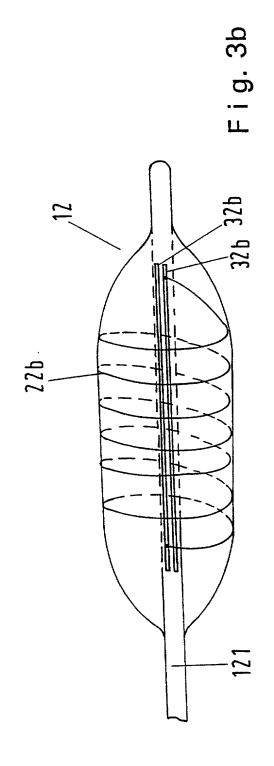




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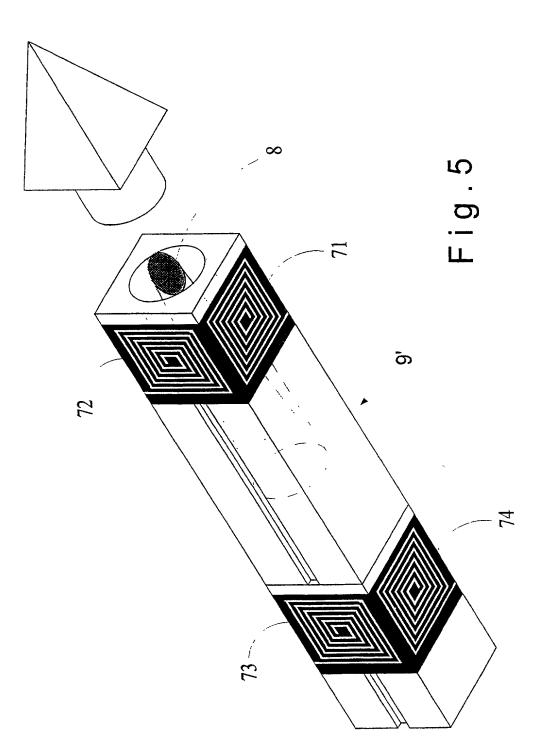




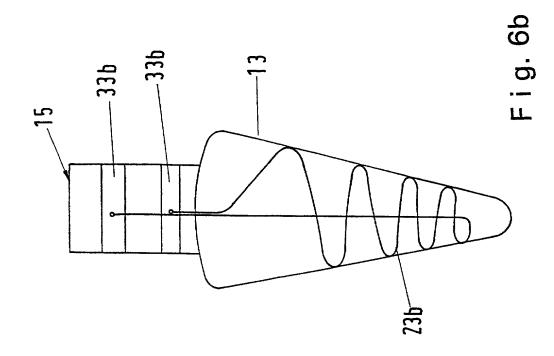
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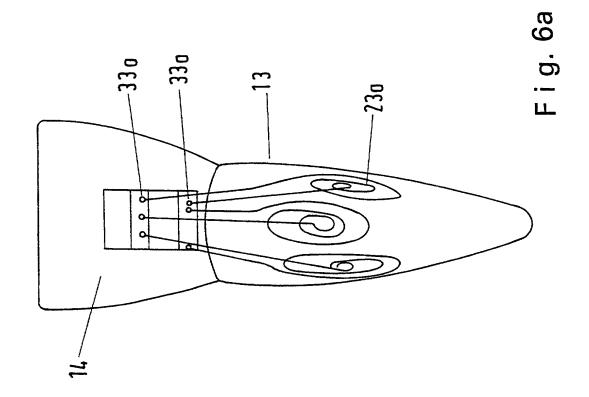
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Fig.4



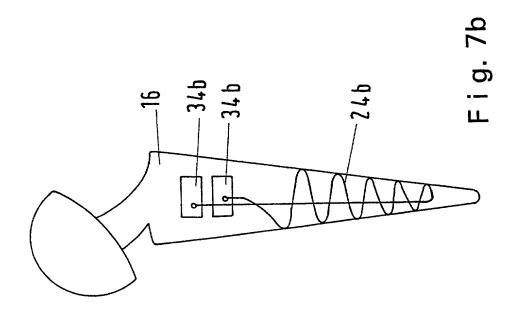
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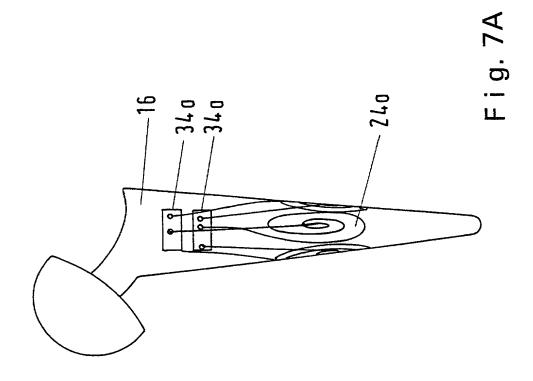




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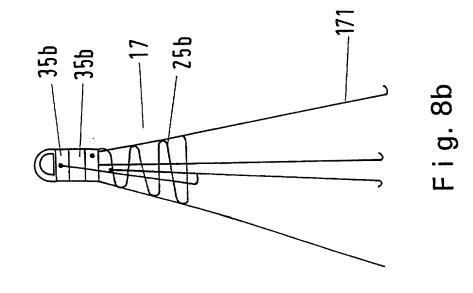
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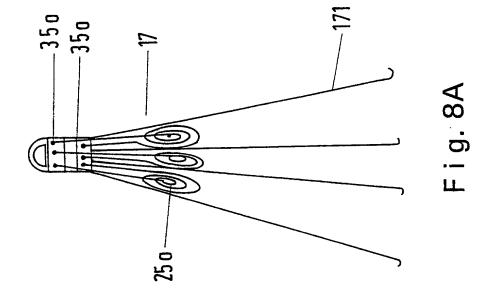


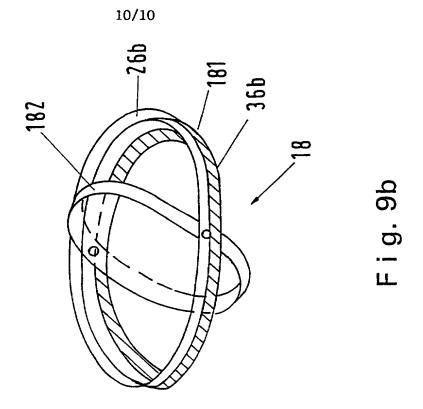


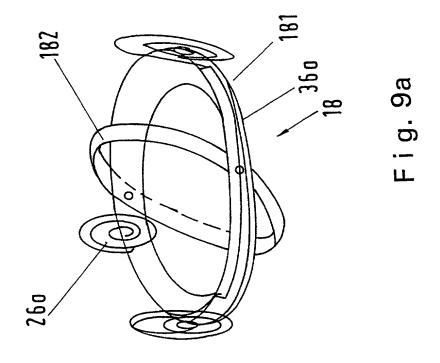
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DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATIONS

PATENT

Docket No.: 37418/DBP/M521

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled MR IMAGING METHOD AND MEDICAL DEVICE FOR USE IN METHOD, the specification of which is attached hereto unless the following is checked:

was filed on <u>13.October.1998</u> as United States Application Number or PCT International Application Number <u>PCT/DE98/03046</u> and was amended on <u>29.November.1999</u> (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of the foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Application Number	Country	Filing Date (day/month/year)	Priority Claimed

197 46 735.0 Germany 13.October 1997 Yes

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

Application Number Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

Application Number Filing Date

Patented/Pending/Abandoned

POWER OF ATTORNEY: I hereby appoint the following attorneys and agents of the law firm CHRISTIE, PARKER & HALE, LLP to prosecute this application and any international application under the Patent Cooperation Treaty based on it and to transact all business in the U.S. Patent and Trademark Office connected with either of them in accordance with instructions from the assignee of the entire interest in this application; or from the first or sole inventor named below in the event the application is not assigned; or from MAIKOWSKI

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATIONS

Docket No. 87418/DBP/M521

<u>& NINNEMANN</u> in the event the power granted herein is for an application filed on behalf of a foreign attorney or agent.

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I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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